Paper No. 19

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte ROBERT R. GRANADOS and PING WANG

Appeal No. 2002-2030 Application No. 09/294,663

ON BRIEF

Before SCHEINER, MILLS, and GRIMES, <u>Administrative Patent Judges</u>. GRIMES, <u>Administrative Patent Judge</u>.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claims 1, 6, and 9. Claims 3, 5, 7, 10, and 20-22 are also pending; the examiner has indicated that these claims are allowable. Claim 1 is representative and reads as follows:

1. A transformed plant, comprising an expression vector, wherein said expression vector comprises a gene encoding an invertebrate intestinal mucin (IIM) protein operably linked to an expression control sequence, such that said transformed plant is capable of expressing said IIM protein.

¹ We do not completely agree with the examiner on this point. See the new ground of rejection <u>infra</u>.

The examiner relies on the following reference:

Dandekar et al. (Dandekar), "Low levels of expression of wild type <u>Bacillus</u> thuringienis var. <u>kurstaki cry</u>IA (c) sequences in transgenic walnut somatic embryos," <u>Plant Science</u>, Vol. 96, pp. 151-162 (1994)

Claims 1, 6, and 9 stand rejected under 35 U.S.C. § 112, first paragraph, as nonenabled and inadequately described. We affirm and enter new a ground of rejection of claims 3, 5-7, 9, 10, 21, and 22.

Background

"Vertebrate epithelial organs are covered . . . with a mucus lining, which serves as a physical barrier between extracellular contents and the epithelial cell surface. . . . The protective functions of the mucosal layer are largely dependent upon heavily glycosylated proteins known as mucins." Specification, page 1. Several vertebrate mucin genes have been sequenced. <u>Id.</u>, page 2. "Studies on invertebrate mucins are very limited in comparison," although several mucin-like invertebrate proteins have been reported. <u>Id.</u>

The specification discloses an "intestinal insect mucin comprising two nearly identical isoforms, IIM14 and IIM22, respectively. The proteins are identical except for slightly different peptide length in some repetitive regions." Pages 3-4. "IIM" stands for "invertebrate intestinal mucin." <u>Id.</u>, page 6. Both isoforms were cloned from <u>Trichoplusia ni</u> (cabbage looper) larvae. <u>Id.</u>, page 4. The IIM14 and IIM22 cDNAs encode 788 and 807 amino acids, respectively. <u>Id.</u>, page 10. The specification provides a sequence analysis of the two <u>T. ni</u> IIM isoforms. See pages 10-13.

The specification also discloses that the <u>T. ni</u> IIM was used to raise anti-IIM antibodies, see pages 14-16, and that the antibodies were used to identify cross-reacting proteins in other insect species. Sixteen of the twenty-one species of insects assayed (including <u>T. ni</u>) contained cross-reacting proteins. See pages 31-32. Of the sixteen cross-reacting species, eight "had high molecular weight bands similar in size to <u>T. ni</u> IIM." Page 33.

Discussion

Claims 1, 6, and 9 stand or fall together. See the Appeal Brief, page 4.

We will consider claim 1 as representative. Claim 1 is directed to a transformed plant comprising an expression vector "encoding an invertebrate intestinal mucin (IIM) protein," such that the transformed plant can express the IIM protein. The examiner rejected the claims as inadequately described and nonenabled.

1. Written description

The examiner rejected the claims as inadequately described. The examiner noted that the claims read on a transformed plant comprising a vector encoding any invertebrate intestinal mucin protein, while the specification discloses only two IIM isoforms from a single insect species. See the Examiner's Answer, pages 7-8. According to the examiner, "[n]o other IIM genes have been isolated, characterized or described. No specific chemical or physical characteristics have been disclosed for these genes or their encoded proteins, other than those from Trichoplusia ni, and a review of literature does not indicate that such characteristics would be well known by a skilled artisan." Id., page 8.

The examiner concluded that "[t]he description of two species [is] not a

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representative sample of the genus and does not provide an adequate written description for the genus." <u>Id.</u>

We agree with the examiner's reasoning and conclusion. The Federal Circuit provided the appropriate standard in <u>University of California v. Eli Lilly & Co.</u>, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The claims in <u>Lilly</u> were directed generically to vertebrate or mammalian insulin cDNAs. <u>See</u> 119 F.3d at 1567, 43 USPQ2d at 1405. The court held that a structural description of a rat cDNA was not an adequate description of these broader classes of cDNAs, because a "written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." <u>Id.</u> (bracketed material in original).

The Lilly court explained that

a generic statement such as . . . 'mammalian insulin cDNA,' without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

<u>Id.</u> at 1568, 43 USPQ2d at 1406. Finally, the <u>Lilly</u> court held that a genus of cDNAs could be described

by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the

members of the genus, which features constitute a substantial portion of the genus.

ld.

The Federal Circuit recently revisited this issue. See Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court clarified that a description of DNA need not, necessarily, disclose its structure. The court adopted the standard that

the written description requirement can be met by "show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

<u>Id.</u> at 1324, 63 USPQ2d at 1613 (emphasis omitted, ellipsis and bracketed material in original).

This standard, of course, applies to describing a single compound. The Enzo court did not decide whether broader genus claims could be described by three deposited DNA sequences; that issue was left for the district court on remand. See id.

Thus, the instant specification can provide an adequate description of claim 1's genus of IIM genes, per <u>Lilly</u>, by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, the specification can describe the genus by describing a "representative number" of IIM genes, where the representative species are described according to the standard of either <u>Lilly</u> or <u>Enzo</u>.

In this case, the specification does not describe generic IIM genes in accordance with either of the above standards. The specification discloses two IIM-encoding cDNAs from <u>Trichoplusia ni</u> in full, structural detail (SEQ ID NO:1 and SEQ ID NO:2). The specification provides no description of any other IIM-encoding nucleic acids.

The specification thus does not describe any structural features common to members of the genus of IIM-encoding genes. The specification's disclosure of the sequence of the cDNAs encoding IIM14 and IIM22 from T. ni (SEQ IDs 1 and 2) does not suffice. The specification provides no description of the structural features that are common to both T. ni genes, and that are also shared by other IIM genes encompassed by claim 1. Since the specification describes no structural features that are common to the members of the genus, it necessarily does not describe structural features that "constitute a substantial portion of the genus," per Lilly.

The specification also does not describe a "representative number" of species within the genus to constitute a description of the full genus. Under either the <u>Lilly</u> or <u>Enzo</u> standard, the specification describes only two species of IIM genes – SEQ ID NO:1 and SEQ ID NO:2. Appellants have provided no evidence to show that the chemical structures of these two species, both isolated from <u>Trichoplusia ni</u>, are in any way representative of the structures of the full genus of IIM genes encompassed by claim 1.

The evidence, in fact, is to the contrary. The specification itself discloses that, out of twenty species of insects tested (not including <u>T. ni</u> (cabbage looper)),

fifteen expressed proteins that were bound by antibody to <u>T. ni</u> IIM. See pages 31-33. Of the fifteen cross-reacting proteins, however, only eight had a molecular weight similar to that of <u>T. ni</u> IIM. See page 33. Since the structure, and therefore the size, of a protein is a function of the DNA that encodes it, the differing sizes of the cross-reacting proteins indicate that the two cDNAs isolated from T. ni are not representative of IIM-encoding DNAs as a genus.

Thus, the evidence supports the examiner's position that a description of two T. ni IIM cDNAs is inadequate to describe the full genus of IIM-encoding genes encompassed by claim 1. Rather, claim 1's recitation of "a gene encoding an invertebrate intestinal mucin (IIM) protein" falls squarely within the category of nucleic acids defined by function, not structure, that were disparaged by the Lilly court. See 119 F.3d at 1568, 43 USPQ2d at 1406 ("A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is."). We therefore agree with the examiner that claims 1, 6, and 9 are not adequately described by the instant specification.

Appellants argue that the specification "substantially defines the essential physical and structural features that characterize IIM proteins." Appeal Brief, page 17. Appellants point to the specification's disclosure that the proteins encoded by the isolated T. ni cDNAs

have an amino acid composition similar to that of a typical vertebrate mucin, . . . and exhibiting the characteristics of high glycosylation, high resistance to protease, stability over a wide pH range, and the presence of strong intermolecular sulfide bonds. The IIM proteins in particular further are characterized by localized

expression in the midgut of invertebrates, chitin binding activity and strong association with the peritrophic membrane, and specific binding with the IIM antibody.

<u>Id.</u> Appellants also argue that these structural features, together with the specification's disclosure of the presence of cross-reacting proteins in other insect species, constitutes a description of a representative number of species from the claimed genus. Appeal Brief, pages 18-19.

This argument is not persuasive. Claim 1 is directed to transgenic plants comprising a generic IIM-encoding gene. The structural features that Appellants rely on are those of the <u>T. ni</u> IIM <u>proteins</u>. Even if we assume, for the sake of argument, that the specification adequately describes a genus of IIM proteins, such a description would not support the instant claims. It is well-established that the amino acid sequence of a protein does not describe the DNA sequence of the gene encoding it. <u>See, e.g., Lilly, 119 F.3d at 1566, 43 USPQ2d at 1405</u> ("Example 6 provides the amino acid sequence of the human insulin A and B chains, but that disclosure also fails to describe the cDNA."). Thus, structural features of IIM proteins cannot be relied on to describe the genus of IIM-encoding genes recited in claim 1.

We therefore affirm the rejection of claim 1 for lack of an adequate written description in the specification. Claims 6 and 9 fall with claim 1.

2. Enablement

The examiner also rejected claims 1, 6, and 9 as nonenabled. The examiner acknowledged that the specification is enabling for transgenic plants comprising an IIM-encoding cDNA from Trichoplusia ni, but concluded that the

specification does not provide "enablement for a transformed plant comprising a gene encoding an intestinal mucin protein of any invertebrate." Examiner's Answer, page 3.

The examiner noted that claim 1 is very broad, in that it encompasses IIMencoding genes from any invertebrate, which includes such divergent organisms as insects, earthworms, mollusks, and crustaceans. See the Examiner's Answer, page 4. The examiner also noted that the specification provides no guidance

for how to obtain other IIM genes from other insect species or other invertebrate species. No other DNA sequence from other insect species, and no protein or DNA sequence from non-insect invertebrate species, has been isolated or characterized. No specific guidance for obtaining the genes such as specific probes, hybridization stringency conditions, or gene sequence similarity has been provided.

<u>Id.</u> (emphasis omitted). The examiner concluded that "[t]o claim transgenic plants expressing a multitude of IIM genes from a multitude of sources without any disclosure or guidance for how to obtain the genes is an invitation to experiment requiring undue and excessive experimentation." Id., pages 5-6.

We agree. The claims are extremely broad, reading as they do on IIM-encoding genes from any invertebrate animal. The specification's working examples, by contrast, are limited to two IIM-encoding cDNAs from a single species of insect (<u>T. ni</u>). As the examiner pointed out, the specification provides no guidance whatever to direct those skilled in the art in practicing the claimed invention more broadly than it is exemplified. The specification does not show, for example, that other insect IIM-encoding genes are substantially similar in sequence to the disclosed <u>T. ni</u> IIM cDNAs. Nor does the specification disclose

that other, similar IIM-encoding genes were known in the art. On the contrary, the specification states "[p]rior to the present invention, no intestinal mucin had been identified from invertebrates." Page 6.

In view of the lack of guidance in the specification and the limited working examples, the breadth of the claims and resulting quantity of necessary experimentation, and the lack of additional guidance in the prior art, we agree with the examiner that practicing the full scope of the claims would have required undue experimentation. Since the claims are not commensurate with the enabling scope of the disclosure, they are not in compliance with 35 U.S.C. § 112, first paragraph.

Appellants do not dispute that "the claims are broad generic claims . . . and the nature of the invention is biological and complex." Appeal Brief, page 10. Appellants also concede that "[c]learly the experimentation needed to practice the invention is extensive and quite complicated." Id., page 11. Appellants argue, however, that such experimentation is considered routine in the field of molecular biology. Id. Appellants also argue that all of the techniques required to isolate other IIM-encoding genes are well known in the art. Id. at 10-11. Appellants conclude that the balance of the Wands factors supports enablement of the present claims.

Appellants' argument is not persuasive. Appellants place heavy reliance on the specification's disclosure that several other insect species express proteins that cross-react with antibodies against <u>T. ni</u> IIM protein. See the Appeal Brief, page 10, last paragraph, and page 11, last paragraph. This

disclosure does little to reduce the experimentation needed to practice the claimed invention. At best, it identifies several insect species that might contain IIM-encoding genes similar in sequence to those of <u>T. ni</u>; the IIM-encoding genes from these species, therefore, might reasonably be expected to hybridize to a probe corresponding to part of the <u>T. ni</u> IIM cDNA.

However, even if the evidence showed that IIM-encoding genes could be isolated from the eight other insect species shown to express 400 kD proteins that cross-react with antibody to <u>T. ni</u> IIM, without undue experimentation, such evidence would not show enablement of the full scope of claim 1. Claim 1 is extremely broad; as the examiner pointed out, the category of invertebrates are not limited to insects, it also encompasses worms, mollusks such as snails and clams, and crustaceans such as lobsters. Appellants have provided no evidence with respect to non-insect invertebrates. Thus, the specification might, at best, provide a starting point for further research, but it does not provide a disclosure that enables practice of the full scope of claim 1 without undue experimentation.

Essentially, Appellants' position is that, even though the specification provides no guidance regarding IIM-encoding genes in species other than <u>T. ni</u>, the claims are enabled because everything needed to practice the full scope of the claims was known in the art. The Federal Circuit has cautioned against overreliance on the rule, cited by Appellants here, that a patent need not teach, and preferably omits, what is well known in the art. <u>See Genentech Inc. v. Novo Nordisk A/S</u>, 108 F.3d 1361, 1366, 42 USPQ2d 1001, 1005 (Fed. Cir. 1997): "[T]hat general, oft-repeated statement is merely a rule of supplementation, not a

substitute for a basic enabling disclosure. It means that the omission of minor details does not cause a specification to fail to meet the enablement requirement.

... It is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement."

The <u>Genentech</u> court also held that, "[w]hile every aspect of a generic claim certainly need not have been carried out by an inventor, or exemplified in the specification, reasonable detail must be provided in order to enable members of the public to understand and carry out the invention." <u>Id.</u> In this case, as in <u>Genentech</u>, the specification does not provide the "reasonable detail . . . to enable members of the public to understand and carry out the invention." It therefore does not satisfy the enablement requirement of 35 U.S.C. § 112, first paragraph, and we affirm the examiner's rejection of claims 1, 6, and 9.

New Ground of Rejection

Under the provisions of 37 CFR § 1.196(b), we make the following new ground of rejection: Claims 3, 5-7, 9, 10, 21, and 22 are rejected under the judicially created doctrine of obviousness-type double patenting, as being directed to an invention that is not patentably distinct from that of claims 1-3 and 6-8 of Appellants' patent 6,187,558.

"Obviousness-type double patenting is a judge-made doctrine that prevents an extension of the patent right beyond the statutory time limit. It requires rejection of an application claim when the claimed subject matter is not

patentably distinct from the subject matter claimed in a commonly owned patent." In re Berg, 140 F.3d 1428, 1431, 46 USPQ2d 1226, 1229 (Fed. Cir. 1998).

Instant claims 3, 5, 7, and 10 compare to claims 1-3 and 6 of the '558 patent as follows:

| Instant claim: | '558 patent claim: |
|---|--|
| 3. A recombinant DNA sequence | 2. An isolated polynucleotide encoding |
| comprising a DNA sequence that | an invertebrate intestinal mucin, said |
| codes for an IIM protein, wherein a | polynucleotide comprising a nucleotide |
| nucleic acid sequence of said | sequence selected from the group |
| recombinant DNA sequence is selected | consisting of: |
| from the group consisting of: | a) SEQ ID No. 1; and |
| a) a cDNA sequence as shown | b) SEQ ID No. 2. |
| in SEQ ID No. 1; and | |
| b) a cDNA sequence as shown | |
| in SEQ ID No. 2. | |
| 5. The recombinant DNA sequence of | An isolated polynucleotide encoding |
| claim 3, wherein said IIM has an amino | an invertebrate intestinal mucin |
| acid sequence selected from the group | comprising an amino acid sequence |
| consisting of: | selected from the group consisting of: |
| a) SEQ ID No. 3; and | a) SEQ ID No. 3; and |
| b) SEQ ID No. 4. | b) SEQ ID No. 4. |
| 7. A gene expression vector containing | 3. An expression vector comprising an |
| a recombinant DNA sequence | expression control sequence |
| encoding a <u>Trichoplusia ni</u> IIM protein | operatively linked to the polynucleotide |
| sequence. | of claim 1 or claim 2. |
| 10. The expression vector of claim 7, | 6. The expression vector of claim 3, |
| wherein said expression vector is a | wherein the expression vector is a |
| recombinant plasmid adapted for | plant expression vector. |
| insertion into and transformation of a | |
| plant. | |

Thus, claims 1 and 2 of the '558 patent are generic to instant claims 3 and 5. That is, the '558 patent's "isolated polynucleotide" is generic to DNA and RNA, either recombinant and nonrecombinant. However, DNA is an obvious form of polynucleotide, in that it is one of only two available options; it is also the form in which polynucleotides are stably found within living cells. And

recombinant DNA is an obvious form of DNA, since the combination of a gene with other DNA sequences (promoters, plasmid vector sequences, etc.) with which it is not naturally found allows the DNA to be expressed in a greater variety of cells and in greater quantities than found in nature. Recombinant DNA is the basis of the entire biotechnology industry. Thus, recombinant DNA comprising a particular DNA sequence is not patentably distinct from the DNA sequence itself.

Similarly, instant claim 10 is directed to an expression vector that is a recombinant plasmid. This claimed product is an obvious species of the "expression vector" recited in the '558 patent's claim 6. Expression vectors are either plasmids or viruses; since a plasmid is one of only two options, a plasmid expression vector is not patentably distinct from a generic expression vector.

In addition, instant claim 7 is generic to the '558 patent's claim 3. That is, claim 7's recitation of the "DNA sequence encoding a <u>Trichoplusia ni</u> IIM protein" encompasses the '558 patent's sequences comprising SEQ ID NO's 1 or 2, as well as sequences encoding SEQ ID NO's 3 and 4. "[A] later genus claim limitation is anticipated by, and therefore not patentably distinct from, an earlier species claim." <u>Eli Lilly & Co. v. Barr Labs., Inc.</u>, 251 F.3d 955, 971, 58 USPQ2d 1869, 1880 (Fed. Cir. 2001).

Instant claims 6 and 9 compare to the '558 patent's claims 7 and 8 as follows:

| 6. A method of producing an IIM protein or peptide comprising: a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence which codes for a predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. 7. A method of producing an invertebrate intestinal mucin protein or peptide comprising: a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence encodes an amino acid sequence encodes an amino acid sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and d) recovering said invertebrate | Instant claim: | '558 patent claim: |
|--|--|--|
| a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence which codes for a predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. peptide comprising: a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence, wherein the nucleotide sequence encodes an amino acid sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | 6. A method of producing an IIM | 7. A method of producing an |
| a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence which codes for a predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence, wherein the nucleotide sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | protein or peptide comprising: | invertebrate intestinal mucin protein or |
| an expression vector comprising a promoter operatively linked to a nucleotide sequence which codes for a predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. a) transforming a host cell with an expression vector comprising a promoter operatively linked to a nucleotide sequence, wherein the nucleotide sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | peptide comprising: |
| promoter operatively linked to a nucleotide sequence which codes for a predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. expression vector comprising a promoter operatively linked to a nucleotide sequence, wherein the nucleotide sequence encodes an amino acid sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | a) transforming a host cell with | |
| nucleotide sequence which codes for a predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. b) culturing said host cell; and d) recovering said IIM protein. promoter operatively linked to a nucleotide sequence, wherein the nucleotide sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | an expression vector comprising a | a) transforming a host cell with an |
| predetermined protein or peptide of an IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. d) recovering said IIM protein. nucleotide sequence, wherein the nucleotide sequence selected from the group consisting of: i) SEQ ID No. 4; or wherein the nucleotide sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | promoter operatively linked to a | expression vector comprising a |
| IIM protein; b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. d) recovering said IIM protein. nucleotide sequence encodes an amino acid sequence selected from the group consisting of: i) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | nucleotide sequence which codes for a | promoter operatively linked to a |
| b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. amino acid sequence selected from the group consisting of: i) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | predetermined protein or peptide of an | nucleotide sequence, wherein the |
| b) culturing said host cell under conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. group consisting of: i) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | IIM protein; | nucleotide sequence encodes an |
| conditions such that said IIM protein is expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. i) SEQ ID No. 3; and ii) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | amino acid sequence selected from the |
| expressed in recoverable quantity; c) lysing said host cell; and d) recovering said IIM protein. ii) SEQ ID No. 4; or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | b) culturing said host cell under | group consisting of: |
| or wherein the nucleotide sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | · · | , |
| c) lysing said host cell; and d) recovering said IIM protein. sequence encodes a peptide comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | expressed in recoverable quantity; | l · · · · · · · · · · · · · · · · · · · |
| d) recovering said IIM protein. comprised by a sequence selected from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | |
| d) recovering said IIM protein. from the group consisting of: i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | c) lysing said host cell; and | |
| i) SEQ ID No. 3; and ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | ı · · · · · · · · · · · · · · · · · · · |
| ii) SEQ ID No. 4; b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | d) recovering said IIM protein. | , |
| b) culturing said host cell under conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | , |
| conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | ii) SEQ ID No. 4; |
| conditions that allow expression of said invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | |
| invertebrate intestinal mucin protein or peptide in recoverable quantity; c) lysing said host cell; and | | |
| peptide in recoverable quantity; c) lysing said host cell; and | | |
| c) lysing said host cell; and | | I |
| | | peptide in recoverable quantity; |
| | | a) lyging gold boot goll; and |
| d) recovering said invertebrate | | c) lysing salu flost cell, and |
| | | d) recovering said invertebrate |
| intestinal mucin protein or peptide. | | |
| 9. The method of claim 6 wherein said 8. The method of claim 7 wherein said | | |
| expression vector further comprises a expression vector encodes a fusion | | |
| gene encoding a transfer molecule protein comprising the invertebrate | 1 - | |
| such as glutathione-S-transferase. intestinal mucin protein or peptide and | such as glutathione-S-transferase. | |
| glutathione-S-transferase. | | glutathione-S-transferase. |

Instant claims 21 and 22 are the same as instant claims 6 and 9 except that claims 21 and 22 are limited to a method of making a "<u>Trichoplusia ni</u> IIM protein," rather than any "IIM protein or peptide."

Thus, instant claims 6, 9, 21, and 22 are generic to the '558 patent's claims 7 and 8. That is, the '558 patent's claims are limited to methods comprising expression of nucleotide sequences encoding SEQ ID NO:3 or SEQ ID NO:4, while the instant claims encompass expression of nucleotide sequences that encode any IIM protein (claims 6 and 9) or any T. ni IIM protein (claims 21 and 22). A later genus claim is not patentably distinct from an earlier species claim. See Eli Lilly v. Barr Labs., 251 F.3d at 971, 58 USPQ2d at 1880.

We therefore conclude that instant claims 3, 5-7, 9, 10, 21, and 22 are not patentably distinct from claims 1-3 and 6-8 of the '558 patent. Claims 3, 5-7, 9, 10, 21, and 22 are therefore properly rejected for obviousness-type double patenting. As far as we can tell, however, the examiner has not rejected any of the claims in this application for obviousness-type double patenting. Nor has the examiner provided a basis, on the record, for concluding that the instant claims are patentably distinct from those of the '558 patent.

The examiner may have concluded that an obviousness-type double patenting rejection could not be made because the claims in both this application and application 09/103,429 (which gave rise to the '558 patent) were subject to a restriction requirement, and different groups of claims were elected in each case. That is, in the parent application, Appellants elected to pursue claims directed to "microorganisms, comprising an expression vector encoding an IIM protein." See the '429 application's Paper No. 7, mailed August 30, 1999 (restriction); and Paper No. 8, filed Nov. 19, 1999 (election). In this application, Appellants elected to pursue claims directed to IIM-encoding genes and transformed plant cells.

See Paper No. 4, mailed Sept. 1, 1999 (restriction) and Paper No. 7, filed Nov. 19, 1999 (election).

It is true that 35 U.S.C. § 121 provides that "[a] patent issuing on an application with respect to which a requirement for restriction . . . has been made . . . shall not be used as a reference either in the Patent and Trademark Office or in the courts against a divisional application . . ., if the divisional application is filed before the issuance of the patent on the other application." This statutory language precludes an examiner from using the earlier application to reject the later one on the basis of obviousness-type double patenting. <u>See MPEP</u> § 804.01.

That general rule, however, only applies where the claims in the two applications are maintained consonant with the restriction requirement. "Consonance requires that the line of demarcation between the 'independent and distinct inventions' that prompted the restriction requirement be maintained. Though the claims may be amended, they must not be so amended as to bring them back over the line imposed in the restriction requirement. Where that line is crossed the prohibition of the third sentence of Section 121 does not apply."

Gerber Garment Technology Inc. v. Lectra Systems Inc., 916 F.2d 683, 688, 16 USPQ2d 1436, 1440 (Fed. Cir. 1990).

The third sentence of § 121 does not preclude a rejection for obviousness-type double patenting in this case. First, the instant case is a continuation-in-part, not a divisional, of the '429 application. It therefore does not fall within the literal terms of the statute. In addition, as the tables above show, the claims in

the two applications have not been maintained consonant with the respective restriction requirements. Therefore, rejection of the instant claims for obviousness-type double patenting is proper.

Summary

We affirm the rejection of claims 1, 6, and 9 for nonenablement and lack of an adequate written description. We also enter new grounds of rejection of claims 3, 5-7, 9, 10, 21, and 22 for obviousness-type double patenting. Thus, claim 20 is not subject to any outstanding rejection.

This decision contains new grounds of rejection pursuant to 37 CFR § 1.196(b). 37 CFR § 1.196(b) provides that "[a] new ground of rejection shall not be considered final for purposes of judicial review."

37 CFR § 1.196(b) also provides that the appellant, <u>WITHIN TWO MONTHS FROM THE DATE OF THE DECISION</u>, must exercise one of the following two options with respect to the new grounds of rejection to avoid termination of proceedings (37 CFR § 1.197(c)) as to the rejected claims:

- (1) Submit an appropriate amendment of the claims so rejected or a showing of facts relating to the claims so rejected, or both, and have the matter reconsidered by the examiner, in which event the application will be remanded to the examiner. . . .
- (2) Request that the application be reheard under § 1.197(b) by the Board of Patent Appeals and Interferences upon the same record. . . .

No time period for taking any subsequent action in connection with this appeal may be extended under 37 CFR § 1.136(a).

AFFIRMED, 37 CFR 1.196(b)

| Toni R. Scheiner Administrative Patent Judge |))) |
|---|------------------------|
| Domotro I Millo |)) BOARD OF PATENT |
| Demetra J. Mills Administrative Patent Judge |)) APPEALS AND |
| |)) INTERFERENCES |
| Eric Grimes Administrative Patent Judge |) |

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